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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,266	10/13/2005	Samuel I Stupp	NANO 107 US2 (NU 22092)	1005
62249	7590	03/27/2007	EXAMINER	
BENET GROUP LLC C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/534,266

Applicant(s)

STUPP ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2,11-16,18 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,17,19-22 and 26 is/are rejected.
- 7) ☒ Claim(s) 7-10 and 23-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Applicants' election of Group I is acknowledged (claims 1-10, 17-26). Also acknowledged are the species/subgenus elections:

The elected bola amphiphile is compound 1 (presented in figure 1); the bola amphiphile is present in a self- assembled micelle (as opposed to a bola amphiphile composition), and the self- assembled micelle is present in combination with water, and the concentration of the bola amphiphile is about 1%.

Claims 11-16, 27-36 are withdrawn pursuant to the restriction. Claims 2 and 18 are withdrawn because they do not encompass the elected bola compound. Claims 1, 3-10, 17, 19-26 are examined in this Office action. Claims 7-10, 23-25 are objected to because of their dependence on rejected claims.

✦

Claim 4 is objected to. The phrase "non-peptide bond forming" should instead be non-peptide bond-forming (i.e., a hyphen between "bond" and forming").

✦

Claims 1, 3-6, 17, 19-21 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a composition. A "composition", however, must have at least two components, otherwise it is a compound. If one has a single, pure compound,

one is not in possession of a composition. Thus, claim 1 effectively mandates the presence of a second compound or material, yet is silent as to what that might be. The same issue applies in the case of claim 17.

In claim 25, the phrase "the one or more" lacks antecedent basis.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 17, 19, 21 are rejected under 35 U.S.C. §102(b) as being anticipated by Kogiso, M. (*Biochimica et Biophysica Acta, General Subjects* 1475(3), 346-352, 2000)

Kogiso discloses the invention substantially as claimed.

Thus, the claims are anticipated.



The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter

and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 5, 17, 21 are rejected under 35 U.S.C. §103 as being unpatentable over Knudsen (USP 6,458,924).

Knudsen discloses various analogs of GLP-1 in which one of the internal lysine groups is acylated with a hydrophobic group. As one of many examples, one could consider the compound of example 64 (col 186, line 20). In this case, the "hydrophobic moiety" would be *gamma*-glutamyl-N-hexadecanoyl-lysine. As it happens, this moiety does have a "first end" and a "second end". The "first end" is the *alpha*-carboxyl group of lysine, and the "second end" is the *alpha*-amino group of lysine.

Knudsen does not apply the term "bola" to his peptides. However, it is evident that many of the disclosed peptides meet the description of instant claim 1, and so the claims are rendered obvious.



Claims 1, 6-10, 22, 26 are rejected under 35 U.S.C. §103 as being unpatentable over Darcy (US 2003/0092672).

Darcy discloses bola amphiphiles which form micelles. Thus the claims are rendered obvious.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "D. Lukton". The signature is fluid and cursive, with the first letter "D" being large and prominent.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER